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October 12, 1999



The Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition Food and Drug Administration 200 C. Street S.W. Washington, DC 20204

Dear Sir/Madam:

This is a notification pursuant to 21 U.S.C. 343(r)(6) that Standard Process Inc., Palmyra, Wisconsin 53156-0904, is making the following statement:

(1) The combination of mineral complexes, orchic CytosolTM extract and other nutrients found in Orchex work together as a potent calmative, to establish balanced function of the central nervous system.*

This statement is made for a dietary supplement containing a proprietary blend of bovine liver, bovine orchic CytosolTM extract, calcium lactate, manganese lactate, porcine stomach, bovine spleen, ovine spleen, soy (bean), defatted wheat (germ), magnesium citrate, bovine brain, and ascorbic acid. Other ingredients include gelatin, niacinamide, water, calcium stearate, potassium para-aminobenzoate, pyridoxine hydrochloride, and natural colors. And the name of the product is Orchex®.

The information contained herein is accurate and Standard Process Inc. has substantiation that the statements are truthful and not misleading.

Sincerely yours,

Ann Holden

Standard Process Inc.

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